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5                   **RECORD OF ORAL HEARING**  
6                   **UNITED STATES PATENT AND TRADEMARK OFFICE**

7  
8                   **BEFORE THE BOARD OF PATENT APPEALS**  
9                   **AND INTERFERENCES**

10  
11  
12                   Appeal 2010-005829  
13                   Application 10/590,808  
14                   Technology Center 1600

15  
16                   Oral Hearing Held: Wednesday, July 6, 2011

17  
18  
19       Before TERESA STANEK REA, LORA M. GREEN, and  
20       FRANCISCO C. PRATS, Administrative Patent Judges

21       ON BEHALF OF THE APPELLANTS:

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1           *The above-entitled matter came on for hearing on Wednesday,*  
2   *July 6, 2011, commencing at 1:55 p.m., at the U.S. Patent and Trademark*  
3   *Office, 600 Dulany Street, 9th Floor, Alexandria, Virginia, before Kevin E.*  
4   *Carr, Notary Public.*

5

6           THE CLERK: Good afternoon. This is Calendar No. 2, Appeal  
7   No. 2010-005829. Mr. Dan Pereira.

8           JUDGE REA: Thank you.

9           Counsel, we're already familiar with the record.

10          MR. PEREIRA: Okay.

11          JUDGE REA: So you don't have to go back to the beginning of  
12 time. So.

13          MR. PEREIRA: (Laughing.)

14          JUDGE REA: Please any time.

15          MR. PEREIRA: Okay.

16          Well, and I'll try to keep my comments brief, and then leave the  
17 floor open for questions.

18          So the invention here is a method for treating specific diseases  
19 related the vasculature system, and coronary obstruction and peripheral  
20 vasoconstriction.

21          I think at issue here with the Court, an issue that you all need to  
22 decide, is whether there would have been a reasonable expectation of  
23 treating those specific diseases, based on the prior art's teaching of the same  
24 compound in the Liu reference for the treatment of other disorders and  
25 specifically in the Examiner's construction of the prior art, diabetes.

26          And the reason why, obviously, we think we're correct, as  
27 opposed to the Examiner, is because the Examiner is focused on certain  
28 aspects of that second reference.

29          And in particular, I would refer to the Sours publication, which  
30 is the second rejection of the three in the obviousness rejection here, which  
31 provides some discussion that there is a correlation between people who

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1 have diabetes and people who have coronary diseases: High blood pressure,  
2 hypertension, things of that nature.

3 But the Applicant's view, or Appellant's view, I guess in this  
4 situation, is that when you read the entire reference, as I believe we all are  
5 supposed to do so, that tight connection that the Examiner seems to make in  
6 the rejection that if you treat diabetes, you're going to treat, you know,  
7 vasoconstriction or peripheral disorders in the circulatory system, that that's  
8 not so tight.

9 There is clear discussion, in the Sours reference, for example,  
10 that says, you know, sometimes when we treat -- in one set of studies, when  
11 we treat the patients with a certain drug, sometimes we exasperate the  
12 condition of diabetes, as opposed to treating it, with drugs such as  
13 hypertensive drugs.

14 Again, this is all in the record. For example, on the first page of  
15 the Sours reference, it says, "Hypertensive patients who were taking Beta  
16 blockers, had a 28 percent higher risk of diabetes than those taking no  
17 medication."

18 Now that then follows that there were some additional studies,  
19 where the showed some benefit with certain types of antihypertensive drugs  
20 that did have an effect on diabetes.

21 Then you have a discussion in Sours, for example, on 1055  
22 through 1056, columns 2 through 1 there, that say, well -- and the focus,  
23 again, of most of this review article of Sours, was you know, what types of  
24 hypertensive drugs could be used, and how they related for diabetes;

25 And one of the aspect of this reference that the Examiner has  
26 focused on in addition to just the abstract, is this Hope trial, which is  
27 discussed starting at 1055.

28 And what the Examiner takes from that, again, is that, well: If  
29 you treat diabetes, you're going to have a reasonable expectation of treating  
30 these coronary diseases, or circulatory diseases.

31 And what this, I think, says is that the ACE inhibitors -- that's  
32 the focus of that Hope study -- may involve changed in blood flow, may

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1 involve a cellular mechanism, could affect the secretion of insulin from the  
2 pancreas, could be a receptor issue, could be any number of things.

3           And so what I think the Appellants have continued to argue,  
4 both in these responses, the appeal brief, and the Reply Brief, is that when  
5 you construct things on paper, and you find this claim -- and I recognize,  
6 you know, the dispute in terms of hindsight -- but if you look at this claim,  
7 and figure out how you would fit the prior art into that claim, then that's  
8 reasonable.

9           But in the reality of the world and the reality of medical  
10 treatments, when you are conducting a set of experiments in human patients,  
11 sometimes it will work, maybe sometimes it won't work.

12           I mean, that's why we have rigorous clinical trials. That's why  
13 we have, you know, multi-drug approaches to even a single disease, let alone  
14 a patient who has a number of diseases:

15           He could have blood pressure, kidney disorders, diabetes,  
16 obesity. You know, they all have a correlation to each other.

17           We all know, from just looking at the news or reading the  
18 literature, that people who are obese have a higher risk of hypertension and  
19 have a higher risk of diabetes, have a higher risk of -- I don't know, I can  
20 probably continue on, but that's probably not relevant.

21           So the point here is that, yes, there is some teaching in the  
22 secondary references that there is a correlation between diabetes and  
23 hypertension, and thus cardiovascular disorders.

24           But given the nature of these teachings, the Appellants disagree  
25 that there would have been a reasonable expectation for using diabetic drugs  
26 to treat cardiovascular conditions, as a general course.

27           JUDGE GREEN: Now if you give this drug to a diabetic  
28 patient, who has hypertension, would you be inherently also treating the  
29 hypertension? Since it treats hypertension as well?

30           MR. PEREIRA: I don't know.

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1           And the reason I don't know, I mean, number one, I'm not a  
2 clinician and I've never done any experiments. But more to the point is  
3 that --

4           JUDGE GREEN: I mean, why wouldn't this drug treat  
5 hypertension in the diabetic patient, as well as a regular patient?

6           I mean, your claim covers treatment to anybody with a  
7 cardiovascular disease, including a patient with diabetes.

8           MR. PEREIRA: Yeah. Right. With or without diabetes. The  
9 claim does cover that. Correct.

10          JUDGE GREEN: Right. So if you're treating a diabetic with  
11 this drug to treat the diabetes, your claim also would encompass treating the  
12 hypertension in that diabetic patient.

13          MR. PEREIRA: Well, potentially.

14          JUDGE PRATS: Well, actually, according to your own spec,  
15 if somebody is suffering from one of these disorders and gets this drug, you  
16 inherently treat it.

17          Correct?

18          MR. PEREIRA: Which disorders? I'm sorry.

19          JUDGE PRATS: Coronary obstruction or peripheral  
20 vasoconstriction.

21          MR. PEREIRA: Right. That is the focus of this application.  
22 So if you use that drug and target those patients, that would be the net result.

23          JUDGE PRATS: And the Examiner is saying: Well, Sowers  
24 discloses that a lot of diabetics are going to have these disorders; so  
25 therefore, it would be obvious, when you administer this to a diabetic, it's  
26 also obvious to administer this to a patient who is going to need treatment  
27 for coronary obstruction or peripheral vasoconstriction.

28          And therefore, you're inherently treating in that diabetic, the  
29 disorder that you cite in your claim.

30          MR. PEREIRA: Yeah. I mean, I guess there's a couple of  
31 points there. This is not a case of inherency, I don't think. Because I don't

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1 think the record's been established that all diabetic patients have these  
2 coronary diseases.

3 JUDGE PRATS: No, but it would be those ones.

4 JUDGE GREEN: Well, you don't have to have all.

5 MR. PEREIRA: Or -- sorry.

6 JUDGE PRATS: So, correct. It's obvious to administer to a  
7 diabetic. Correct?

8 MR. PEREIRA: Well, that's what Liu teaches.

9 JUDGE PRATS: That's what Liu teaches. It's also obvious that  
10 diabetics disproportionately suffer from these two diseases that are in your  
11 claim, correct?

12 MR. PEREIRA: I wouldn't say that necessarily the evidence  
13 shows it's disproportionately that diabetic patients suffer; it's just a common  
14 thing that happens in diabetic patients is these coronary diseases.

15 JUDGE GREEN: So a large percentage of diabetic patients  
16 would be suffering from these diseases?

17 MR. PEREIRA: Right. But there are probably -- and I don't  
18 have numbers at the tip of my fingers -- but there are probably a large  
19 number of patients who have cardiac problem or circulatory problems, that  
20 have no diabetes whatsoever.

21 JUDGE PRATS: Correct. But I think what the Examiner is  
22 saying is it would be obvious to administer this agent to a diabetic who also  
23 suffers from coronary obstruction or peripheral vasoconstriction;

24 And therefore, once you administer it to that patient, you  
25 inherently get the effect that's described in your specification.

26 And I think that's a pretty good argument.

27 MR. PEREIRA: Well, I mean, I'd have to go back to where I  
28 started, with that we just don't think there is a reasonable expectation of  
29 success, based on the record of the references;

30 Because you know, what Sowers and the other reference,  
31 Parassis, teaches, is the correlative aspects of that argument.

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1           Liu provides a one-paragraph notation that says: Well, you can  
2 use these for any number of diseases: Diabetes, inflammatory, washing your  
3 car.

4           I'm sorry, that's a joke.

5           JUDGE GREEN: But I'm just not seeing --

6           MR. PEREIRA: It's that, you know, you can construct a  
7 treatment regimen on paper; but we don't believe that in the context of one  
8 of ordinary skill in the art, that they would have recognize that they would  
9 have a reasonable expectation of success in using Liu's compounds for the  
10 treatment of generally different types of disorders.

11           JUDGE GREEN: Well, see, that's where I don't understand  
12 where the reasonable expectation of success comes in; because you're  
13 treating a diabetic patient with this drug. I mean, that's the primary  
14 reference, Liu.

15           MR. PEREIRA: Right.

16           JUDGE GREEN: And Sowers --

17           MR. PEREIRA: Well, there is a suggestion for that, correct.

18           JUDGE GREEN: Sours teaches that there is a correlation  
19 between diabetes and cardiovascular diseases --

20           MR. PEREIRA: Right --

21           JUDGE GREEN: A large part of that.

22           So once you start treating the diabetic, aren't you going to be  
23 inherently treating this amount, these other diseases that your specification  
24 teaches?

25           Unless there's something on the record that you have different  
26 amounts, if you treat a diabetic with different amounts than you treat  
27 cardiovascular diseases, or something else.

28           MR. PEREIRA: Right. Yeah.

29           JUDGE GREEN: I didn't see any argument like that, but  
30 maybe there's something in the record.

31           MR. PEREIRA: Right.

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1           No, yeah, there is no record as of today, for sure, that indicates  
2 that there is, you know, different dose intervention, or what not, addressing  
3 the latter point of your comment.

4           But coming back to the aspect, well, if you use the compounds  
5 to treat diabetes, that you wouldn't necessarily presume to expect that you  
6 could also treat these other disorders;

7           And I think that's where the disagreement on the Sowers  
8 reference comes in, is because Sowers says: Well, sometimes you use  
9 hypertensive drugs, or sometimes you use certain types of drugs. And they  
10 have no effect, and sometimes they do the opposite to what you would have  
11 expected;

12           That is, that if the commonality or the link between  
13 hypertension and diabetes is as reasonably as it would seem, then in all  
14 indications where you use a drug for treating hypertension or you use a drug  
15 for treating diabetes, then the expectation would be that you would have an  
16 overall positive effect.

17           And I think that the evidence within the Sowers reference, I  
18 mean, there is no extraneous evidence, no other documents that the  
19 Appellants have cited that lends them to believe that there just isn't a  
20 reasonable expectation of success for using that type of drug in a regimen for  
21 treating cardiovascular diseases.

22           JUDGE GREEN: Well, I guess with the inherency argument,  
23 though, you don't have to recognize the property. You don't have to  
24 recognize the property of that compound; because I mean, that's the whole  
25 point behind inherency is that you can have both recognized and  
26 unrecognized properties of that compound.

27           MR. PEREIRA: Sure.

28           JUDGE GREEN: So the fact that the reference didn't recognize  
29 that it's also teaching cardiovascular disease, you're still treating the same or  
30 overlapping patient populations with the same drug; and we're just trying to  
31 see how your claim would fall outside of that.

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1                   JUDGE REA: Counsel, I think you're arguing your claim  
2 narrower than how it now reads. So you're focusing on the non-diabetic  
3 population.

4                   But the diabetic, when administered these methylene amides,  
5 are being given that medication because they're diabetics.

6                   Diabetics have difficulty with their circulatory system. It  
7 makes sense that the circulation of their heart may be affected by their  
8 disease state, and they would get some benefit from it.

9                   MR. PEREIRA: Yes.

10                  Anyway, to answer the -- I do recognize that the claim -- and I  
11 think we conceded that in the initial appeal brief -- that the claim covers, you  
12 know, whether or not the patient has diabetes, I mean, that the scope of the  
13 claim does encompass both diabetic patients and non-diabetic patients.

14                  You know, I mean, the aspect of inherency, I don't know if it  
15 was being applied on a 102 Anticipation Rejection; I think the argument  
16 would be, quite simply, that there is evidence in the record that not all  
17 diabetic patients have cardiovascular diseases;

18                  And so there are distinct different populations; although there  
19 are potentially -- and there is, from the record -- a point of overlap.

20                  But still, even if you administer to the diabetic patient, I think  
21 what Sours is describing -- if you read the reference in its entirety -- is that if  
22 you treat diabetes, you are not necessarily going to be treating  
23 cardiovascular disorders.

24                  Because, for example, yes diabetes and insulin resistance or any  
25 of the associated --

26                  JUDGE REA: Because it's a different dosage form?

27                  MR. PEREIRA: But it's a different disease. They have  
28 different -- you know, there are commonalities, in terms of there can be, for  
29 example, where I was going with this is, is that:

30                  Diabetes can be, you know, a causative agent for cardiovascular  
31 diseases; and cardiovascular diseases, perhaps, can also be a causative agent  
32 for diabetes.

1           However, there are a number of different factors that go into  
2 whether or not cardiovascular diseases, as a matter of course, will develop.  
3 And that could be genetic predispositions, environmental conditions, and  
4 other cellular enzymatic mechanisms that are unrelated to diabetes.

5           And what they're saying is that: Just because you have two  
6 conditions in a single patient, that have some correlation, that there isn't  
7 necessarily an nexus between those;

8           And our view of Sours is that you wouldn't have a reasonable  
9 expectation that if you would treat diabetes, you would also have an  
10 expectation of treating the other conditions;

11          Because in some instances, when they use hypertensive drugs,  
12 there were negative effects, that is, increased incidences of diabetes. And  
13 Sours itself says this mechanism may have nothing to do with blood flow or  
14 the cardiovascular system may rely on some cellular enzymatic mechanism.

15          And if you're targeting, for example, in using some of the drugs  
16 in the Sours reference, that if you're targeting a cellular enzymatic  
17 mechanism, specifically related to the pancreas, let's say, or some hormonal  
18 release from the brain, that affects insulin secretion from the pancreas, that is  
19 probably not going to have a reasonable effect on the cardiovascular  
20 condition.

21          I mean, believe me, I understand all of your points, in terms of  
22 the inherency and the administration to the diabetes.

23          But what I think the nature of the references are, is that that isn't  
24 clear-cut; it's very cloudy, as to terms of what will happen, could happen,  
25 when you use a drug that, you know, has never been specifically taught or  
26 discussed as being useful for treating those types of cardiovascular  
27 conditions.

28          JUDGE REA: I don't have --

29          JUDGE PRATS: The only teaching we have as to who should  
30 receive these drugs is Liu. Right?

31          MR. PEREIRA: Yes.

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1                   JUDGE PRATS: And so the list is the types of diabetes,  
2        obesity, autoimmune, inflammation, osteoporosis, and some cancer.

3                   Now the Examiner also sort of suggested that obesity might  
4        come under the patient population that would need treatment for the claim  
5        disorders.

6                   Is there any evidence to support that?

7                   MR. PEREIRA: Support which?

8                   JUDGE PRATS: Support that obesity is somehow linked to  
9        cardiovascular obstruction, or peripheral vasoconstriction?

10                  Because the Examiner has kind of intimated that, when he  
11      argues --

12                  MR. PEREIRA: Yeah. I don't recall specifically whether there  
13      has been, you know -- I've been focusing more on the diabetic angle, of  
14      course.

15                  But I mean, I probably have to say that, you know, I know from  
16      just the general news and you know, the scientific literature, that obese  
17      people do have a higher propensity to have cardiovascular conditions, as a  
18      result of their, you know, increased weight and particularly also the strain  
19      that that provides to the heart, when having to pump blood through, you  
20      know, that type of system.

21                  Typically also you end up -- people who are obese have higher  
22      cholesterol levels, have higher fatty deposits, and arteries, which will also  
23      then cause vasoconstriction, as well.

24                  Again, that's sort of generalized, but the evidence of record has  
25      been established, I think, in that regard.

26                  JUDGE PRATS: Thank you.

27                  JUDGE REA: We have nothing further.

28                  MR. PEREIRA: All right. Well, thank you very much. Enjoy  
29      the rest of your afternoon.

30                  JUDGE PRATS: Thanks very much.

31                  JUDGE REA: Thank you.

32                  (Whereupon, at 2:10 p.m., the proceedings were concluded.)

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